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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/806,036	07/05/2001	Mark Leslie Smythe	36677.29	3406
27683	7590	08/17/2006	EXAMINER	
HAYNES AND BOONE, LLP 901 MAIN STREET, SUITE 3100 DALLAS, TX 75202			KAM, CHIH MIN	
			ART UNIT	PAPER NUMBER
			1656	

DATE MAILED: 08/17/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.		Applicant(s)	
	09/806,036		SMYTHE ET AL.	
	Examiner		Art Unit	
	Chih-Min Kam		1656	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 05 June 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 8-19, 32-35, 39, 40 and 44-52 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 32-35, 39, 40, 51 and 52 is/are allowed.
- 6) ☒ Claim(s) 8-19 and 44-50 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Status of the Claims

1. Claims 8-19, 32-35, 39, 40 and 44-52 are pending.

Applicants' amendment filed on June 5, 2006 is acknowledged. Applicants' response has been fully considered. Claims 8, 19, 32, 33, 46 and 48 have been amended. Thus, claims 8-19, 32-35, 39, 40 and 44-52 are examined.

Withdrawn Claim Objections

2. The previous objection to claim 19 is withdrawn in view of applicant's amendment to the claims, and applicant's response at page 17 of the amendment filed June 5, 2006.

Withdrawn Claim Rejections-Obviousness Type Double Patenting

3. The previous rejection of claims 8-19, 32-35, 39, 40 and 46-52 under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-21, 23, 30, 31 and 35 of co-pending application 09/787,840, is withdrawn in view of applicant's submission of a terminal disclaimer, and applicant's response at pages 17-18 of the amendment filed June 5, 2006.

Withdrawn Claim Rejections - 35 USC § 112

4. The previous rejection of claims 8-19, 32-35, 39, 40 and 44-52 under 35 U.S.C. 112, second paragraph, regarding the terms "P is an amino acid" and "preparing a linear peptide of General Formula III", is withdrawn in view of applicant's amendment to the claims, and applicant's response at page 18 of the amendment filed June 5, 2006.

New Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

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The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

5. Claims 8, 12-19 and 44-50 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claims 8, 12-19 and 44-50 are directed to a method of synthesis of a cyclic peptide or peptidomimetic compound of general formula I or II either in solution or via solid-phase synthesis by preparing a linear peptide or peptidomimetic compound of general formula III containing A1 and A2, where A1 is an N-substituent or a chemical moiety that forces a cis amide bond conformation, A2 is reactive functional group to form an initial large cyclic peptide prior to ring contraction to the desired substituted cyclic peptide, and L is a linker between any atom of the peptide and the solid support. While the specification indicates the present invention is using the combination of inducing flexibility in the peptide backbone, through reversible or irreversible N-substitution or forcing cis-amide bond conformations via cis-amide bond surrogates, with novel ring contraction chemistry to preorganize peptides and facilitate the cyclization reaction in solution; and combining one or more of these preorganizing technologies with novel linkers which provide attachment between peptide and resin, to provide a solid phase strategy for the mild, efficient synthesis of cyclic peptides or cyclic peptide libraries (page 12, lines 14-25), the specification does not disclose the synthesis of any cyclic peptidomimetic compound in the claimed method, nor describes a genus of variants for cyclic peptidomimetic compounds.

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Although the specification describes the use of HnB as a backbone substituent and a ring contraction moiety for cyclic peptide synthesis in solution (Example 3), or on the solid support, where an activated linker or a safety catch linker is used to attach the peptide to the resin at C-terminus carboxyl group (Example 8), or a backbone linker is used to anchor the peptide to the resin at first N-amide of C-terminus (Example 11), the specification does not describe the use of various A1 and A2 in the synthesis of any cyclic peptidomimetic compound in the claimed method. Furthermore, there are no examples indicating the use of A1 and A2 in the synthesis of cyclic peptidomimetic compound. The lack of description on the synthesis of a cyclic peptidomimetic compound, and the lack of representative species as encompassed by the claims, applicants have failed to sufficiently describe the claimed invention, in such full, clear, concise terms that a skilled artisan would not recognize applicants were in possession of the claimed invention.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

6. Claims 8-19 and 44-50 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

7. Claims 8-19 and 44-50 are indefinite because the claim lacks essential steps to synthesize cyclic peptide or peptidomimetic compound of General Formula II which has a linker unit (L) linking the cyclic peptide or peptidomimetic compound to a solid support. The claims are also indefinite as to the cycle is a monocycle, bicycle or higher order cycle comprising 1

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monomer, it is not clear how one monomer can form a cyclic peptide or peptidomimetic compound. Claims 9-19 and 44-50 are included in the rejection because they are dependent on rejected claims and do not correct the deficiency of the claim from which they depend.

Response to Arguments

Applicants indicate claim 8 has been further clarified with respect to the definition of L in general formula II as a linker unit that links the cyclic peptide to the solid support, and the claim has also been clarified with respect to clarifying the step of preparing a "linear peptide or peptidomimetic compound" of General Formula II, wherein P is defined as a linear peptide or peptidomimetic compound of 2 to 15 monomers (page 18 of the response).

Applicants' response has been considered, however, the arguments are not found persuasive because there are no method steps indicating the making of the cyclic peptide or peptidomimetic compound of General Formula II.

8. Claim 19 is indefinite because of the use of the term "substituted alkyl,substituted heteroaryl" in R^3 , R^4 and R^5 . The term cited renders the claim indefinite, it is not clear what group is used as a substituent in the substituted alkyl, substituted aryl, substituted arylalkyl or substituted heteroaryl for R^3 , R^4 and R^5 .

9. Claims 46 and 48 are indefinite because the structures of A2 in the claim contain an NH group, while A2 (e.g., 6-nitro-2-hydroxybenzyl) should not contain an NH group, which belongs to the peptide.

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Conclusion



10. Claims 8-19 and 44-50 are rejected. It appears claims 32-35, 39, 40 and 51-52 are free of art.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Chih-Min Kam whose telephone number is (571) 272-0948. The examiner can normally be reached on 8.00-4:30, Mon-Fri.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kathleen Kerr can be reached at 571-272-0931. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Chih-Min Kam, Ph. D.
Primary Patent Examiner

  **CHIH-MIN KAM
PATENT EXAMINER**

CMK

August 15, 2006